

## Regional Drugs Testing Laboratory Directorate General of Health Services, Guwahati (India)-781022 Fax: 0361-2338555/2330555 Phone No.0361 2338555

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## **FORM 13**

(See rule 46)

CERTIFICATE OF TEST OR ANALYSIS BY GOVERNMENT ANALYST UNDER SECTION 25(1) OF THE DRUGS AND COSMETICS ACT, 1940

1. Name of Inspector from whom received

: Mrs. C. Ramdinmawii

Assistant Director (Food & Drugs) C.M.O. Office, Champhai-796321

Mizoram.

2. Serial No. and date of Inspector's memorandum

: 010/IPA-CPI/24

Date: 27/11/2024

3. Number of Sample

:Nil

4. Date of receipt

:11-DEC-2024

5. Names of drugs purporting to be contained in the sample: Telmisartan and Hydrochlorothiazide Tablets IP (Tellme-40H)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2025- 26/0058	GUW/LS/2025- 26/64	TL-23297	DEC. 2023	NA T	Horizon Bioceuticals Pvt. Ltd., Plot No. 3 & 3-A, Industrial Area,
a.			NOV. 2025		Trilokpur Road, Kala Amb, Distt. Sirmour (HP) -173030.

6. Condition of seals on

[the packet or on portion of sample or container]

Seals were intact & identical to the Specimen impression of the seal received from Drugs Inspector

7. Result of test or analysis with protocols or test or analysis applied :Please see below

Date of Testing: From 22-Jan-2025 To 07-Apr-2025

COMPOSITION

Each uncoated tablet contains:

Telmisartan

IP 40 mg

Hydrochlorothiazide

IP 12.5mg

Protocol Applied: I.P. 2022

Sr No.	Test Name	Result	Limits	
1	Description	Bi-layer (orange & off -white), bi-convex, uncoated tablet in alu-alu blister pack.	NA	
2	Identification	Gives positive test for Telmisartan and Hydrochlorothiazide.	NA	
3	Average weight	0.2373 gm.	NA	
4	Uniformity of weight	Complies	NA	
5	Dissolution	Complies.	NA	
6	Dissolution for Telmisartan	Complies (Release of all six units were found above 'Q' 80+5%).	NLT 80 % of claim	
7	Dissolution for Hydrochlorothiazide	Complies (Release of all six units were found above 'Q' 80+5%).	NLT 80 % of claim	

## Assay

Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
Telmisartan	39.33 mg/Tablet	40 mg/Tablet	98.325	95 % to 105 %	
Hydrochlorothiazide	12.84 mg/Tablet	12.5 mg/Tablet	102.72	90 % to 107.5 %	I.P. 2022
		oc.oo mg/rabict	40 mg/rablet	Telmisartan 39.33 mg/Tablet 40 mg/Tablet 98.325	Telmisartan 39.33 mg/Tablet 40 mg/Tablet 98.325 95 % to 105 %

In the opinion of the under signed the sample referred to above **is of standard quality** as defined in the Drugs and Cosmetics Act, 1940, and Rules thereunder for the reasons given below:-

The sample conforms to I.P. with respect to the above tests only.

Date: 09-APR-2025

GOVERNMENT ANALYST

Dilip Kr. Sarkar Government Analyst R.D.T.L., Guwahati-22

